FDA 510(k) Notification

Cordis AMIIA PTA Balloon Dilatation Catheter

MAR 07 2007

Section 3: 510(k) Summary (21 CFR 807.92)

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Date Prepared **November 23, 2006.**

Trade Name **Cordis AMIIA™** Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter.

Classification Name & Device Classification

Classification Name:	Percutaneous Catheter (21 CFR 870.1250)
Classification:	Class II
FDA Classification Panel:	Cardiovascular
Product Code:	LIT

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Predicate Device(s)

The predicate devices for the subject **Cordis AMIIA** PTA Balloon Dilatation Catheter are:

- **Cordis AMIIA** PTA Balloon Dilatation Catheter, which was determined substantially equivalent by FDA (ref. 510(k) number #K050645, dated April 1, 2005).
- Boston Scientific **Sterling Monorail** PTA Balloon Dilatation Catheter. This device was determined substantially equivalent by FDA (ref. 510(k) number #K053118, dated December 16, 2005.

Device description

The Cordis AMIIA PTA Balloon Dilatation Catheter is a catheter with a distal DURALYN™ inflatable balloon. The catheter utilizes a Rapid Exchange design, consisting of a single inflation lumen and a distal guide wire lumen. The guide wire lumen begins at the distal tip and terminates at the guide wire exit port. The guide wire exit port (hole) is approximately 25 cm from the distal tip. The maximum guide wire diameter that may be used is printed on the package label. The catheter tip is tapered to facilitate crossing of tight lesions.

The proximal hub is used as a balloon inflation port. The balloon is inflated by injecting diluted contrast medium through this hub. Two radiopaque marker bands within the balloon indicate the dilating section of the balloon and aid in balloon placement. The nominal balloon diameter and length are printed on the identification band near the hub.

The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. Consult the compliance table incorporated with the product, for diameters of the balloon at given pressures. The design of this catheter does not incorporate a lumen for distal dye injection.

The balloon catheter with a usable shaft length of 142 cm has two proximal shaft markers (90 cm and 100 cm from the distal tip). Both indicate the relative position of the catheter tip to the distal end of the guiding catheter. An additional marker is located at the distal port exit notch and aids in locating the guide wire exit.

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Intended Use

The Cordis AMIIA PTA Balloon Dilatation catheter is intended for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal, and carotid arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
This device is also indicated for post dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Safety and Performance Data

The safety and effectiveness of the subject Cordis AMIIA PTA Balloon Dilatation Catheter has been demonstrated via data collected from non-clinical design verification tests and analyses. No biocompatibility test was required, as the original device has not changed and there was no change in the vascular application of the device [circulating blood contact with limited duration (< 24h.)].

Substantial Equivalence

In summary, the subject Cordis AMIIA PTA Balloon Dilatation Catheter is, in our opinion, substantial equivalent to the predicate devices with respect to intended use, materials, fundamental design and technology, sterility and operating principles.

Substantial Equivalence Statement

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval.
The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 07 2007

Cordis Europa, N.V.
c/o Mr. Harm Hovinga
Senior Regulatory Affairs Associate
Oosteinde 8
9301 LJ Roden
The Netherlands

Re: K063563
Trade/Device Name: Cordis AMIIA PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: February 8, 2007
Received: February 9, 2007

Dear Mr. Hovinga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA 510(k) Notification

Cordis AMIIA PTA Balloon Dilatation Catheter

Section 2: Intended Use Statement

510(k) Number (if known): **K063563**

Device Name: **Cordis AMIIA PTA Balloon Dilatation Catheter**

Indications for Use Statement

The **Cordis AMIIA** PTA Balloon Dilatation catheter is intended for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal, and carotid arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Prescription Use: X OR Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K063563